

US012016578B2

(12) **United States Patent**
Larche et al.

(10) **Patent No.: US 12,016,578 B2**
(45) **Date of Patent: Jun. 25, 2024**

(54) **SURGICAL METHOD FOR OPENING WEDGE OSTEOTOMY AND EQUIPMENT FOR IMPLEMENTING SAME, AND SURGICAL GUIDE DEVICE AND METHOD FOR OBTAINING SAME**

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(*) Notice: Subject to any disclaimer, the term of this
patent is extended or adjusted under 35
U.S.C. 154(b) by 0 days.

(21) Appl. No.: **17/663,025**

(22) Filed: **May 12, 2022**

(65) **Prior Publication Data**

US 2022/0265286 A1 Aug. 25, 2022

Related U.S. Application Data

(62) Division of application No. 16/640,888, filed as
application No. PCT/EP2018/072461 on Aug. 20,
2018, now Pat. No. 11,399,849.

(30) **Foreign Application Priority Data**

Aug. 22, 2017 (FR) 1757798

(51) **Int. Cl.**

A61B 17/17 (2006.01)

A61B 17/80 (2006.01)

(Continued)

(52) **U.S. Cl.**

CPC **A61B 17/1764** (2013.01); **A61B 17/8095**
(2013.01); **A61B 17/864** (2013.01); **A61B**
2017/00526 (2013.01)

(58) **Field of Classification Search**

CPC .. **A61B 17/151**; **A61B 17/152**; **A61B 17/8095**
See application file for complete search history.

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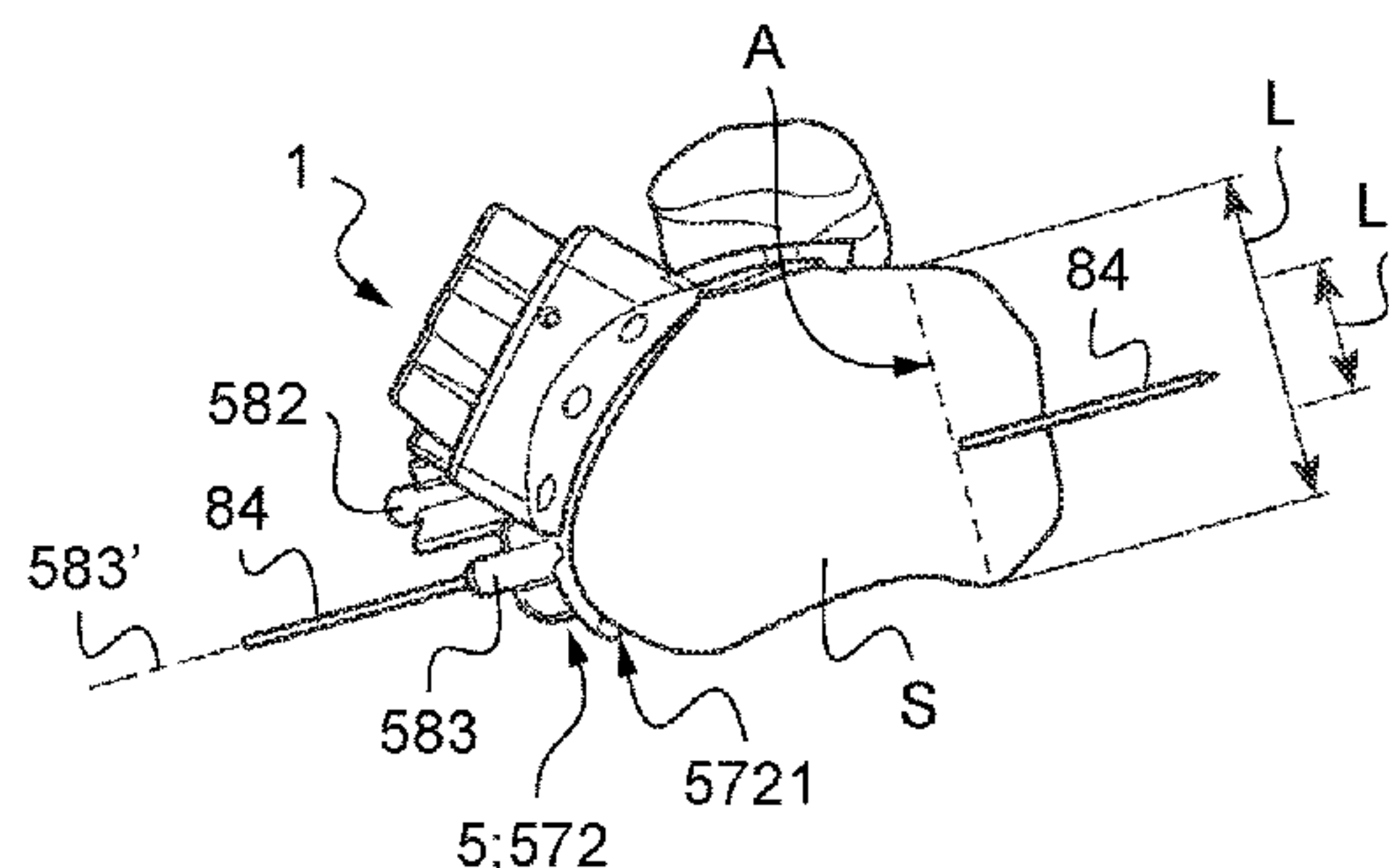
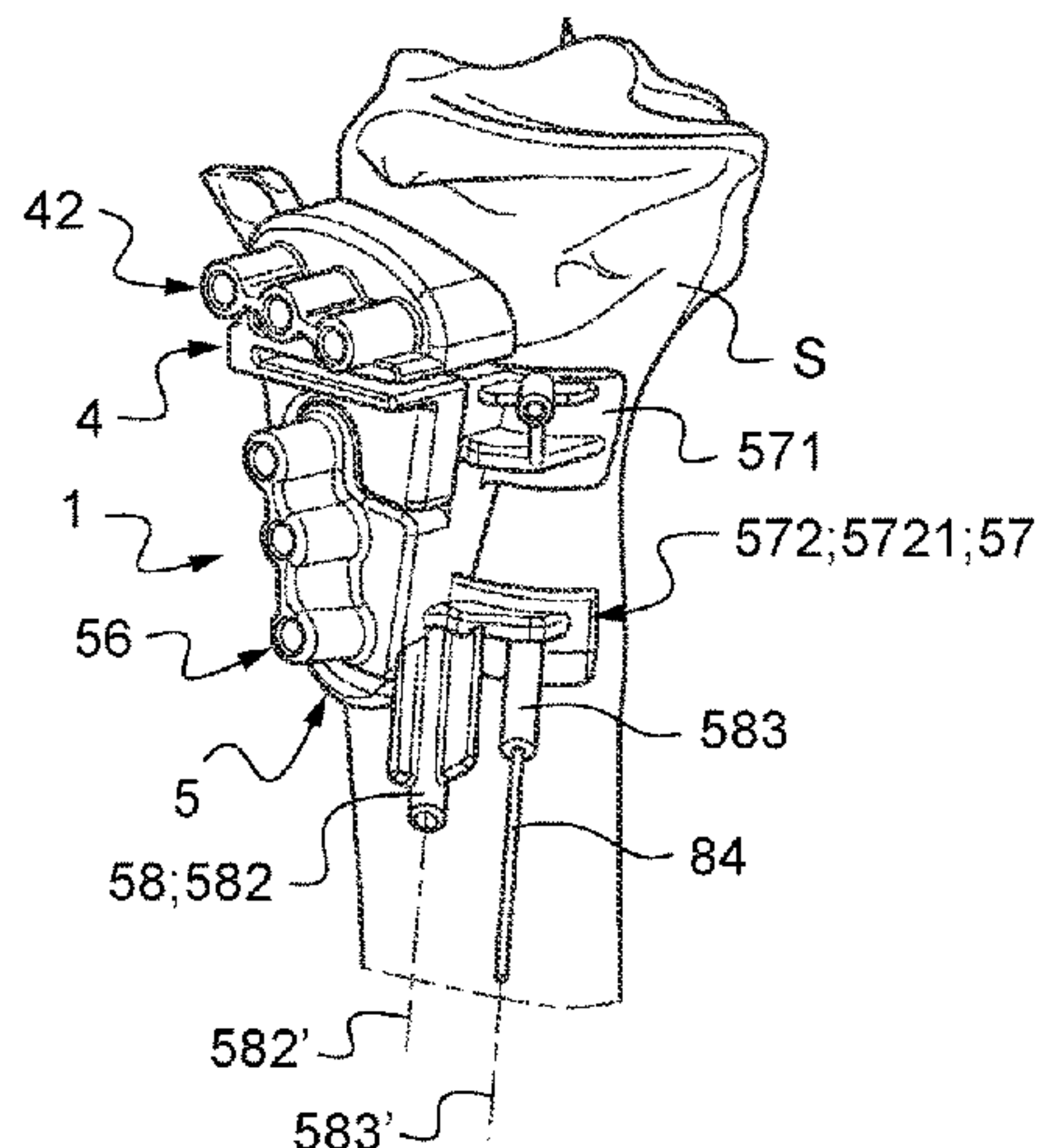
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ABSTRACT

A surgical guide device can be attached to a patient's bone
for assisting an open wedge osteotomy. This device includes
two parts which are joined together by way of removable
securing unit, namely: a proximal part, including a lower
border defining at least one portion of the upper edge of a
guide window, and a distal part having an upper edge
defining at least one portion of the lower edge of the guide
window. The proximal and distal parts are each provided
with a plurality of through holes adapted for receiving
members temporarily implantable in the bone and/or
adapted to guide a drilling of holes in the bone. The

(Continued)



arrangement of the through holes of the surgical guide device advantageously takes into account the planned open wedge osteotomy and anticipates the final position of the screw locations of the reported osteosynthesis plate for freezing the two bone fragments.

8 Claims, 5 Drawing Sheets

(51) **Int. Cl.**
A61B 17/86 (2006.01)
A61B 17/00 (2006.01)

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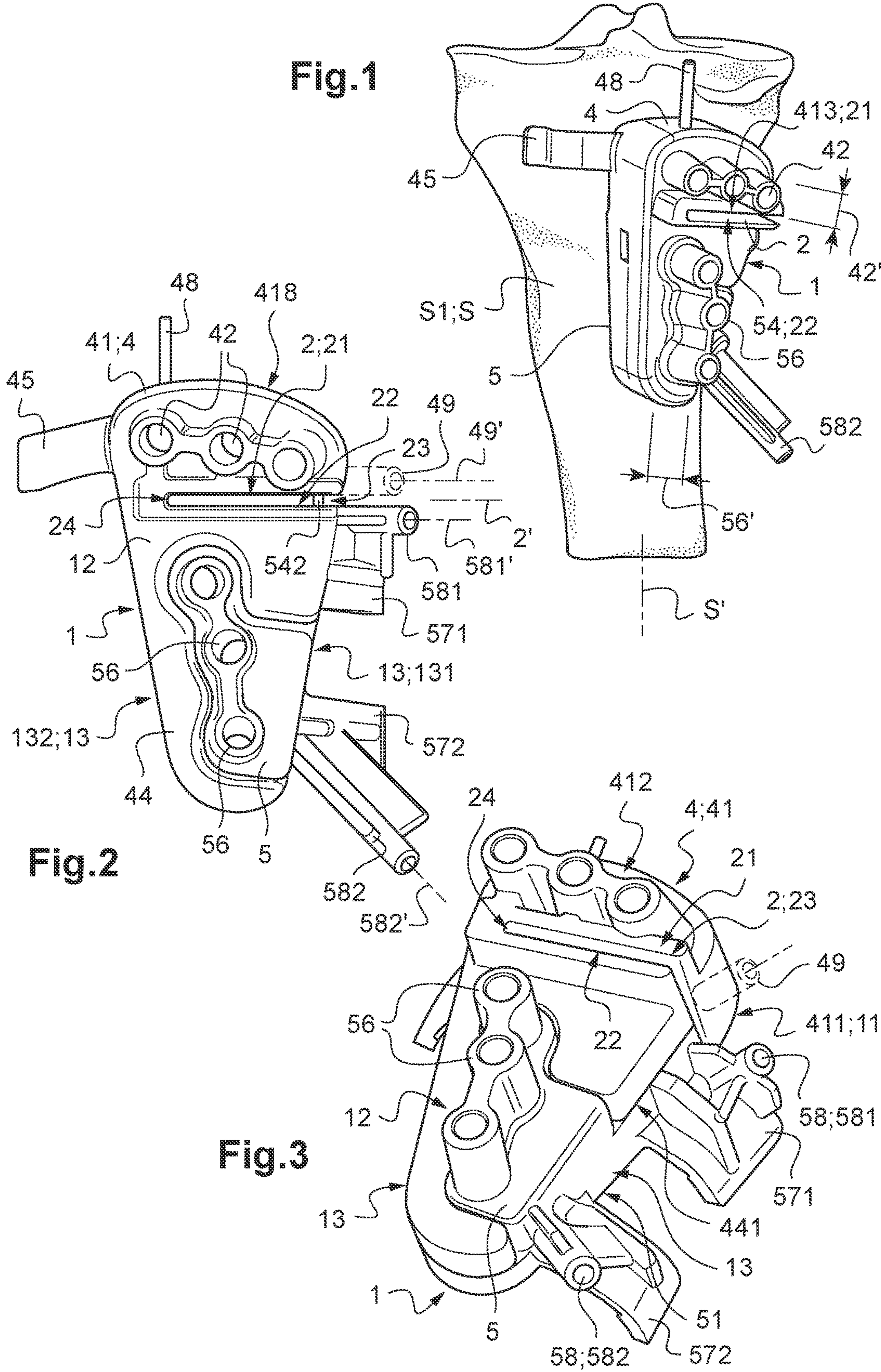


Fig.4

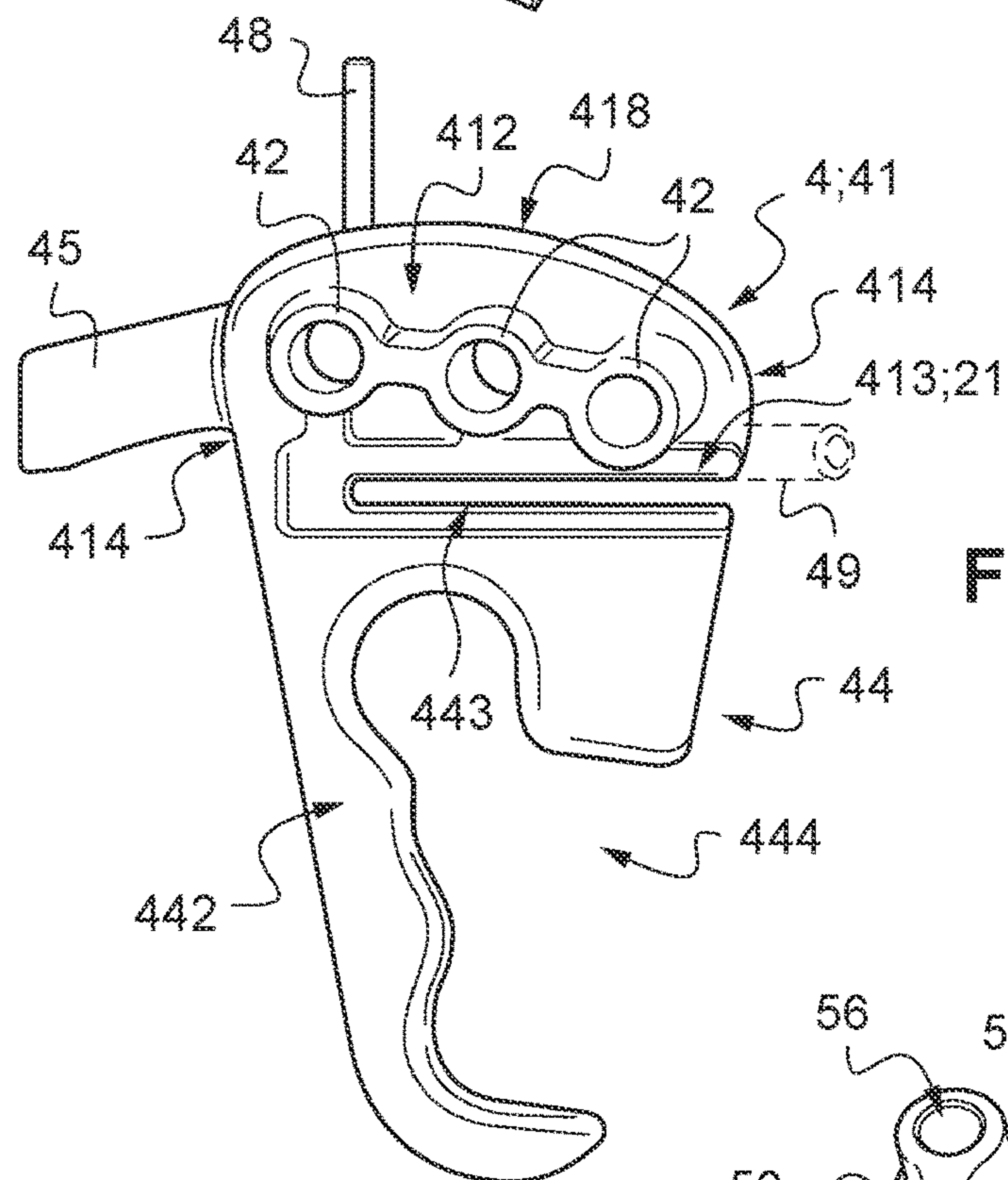
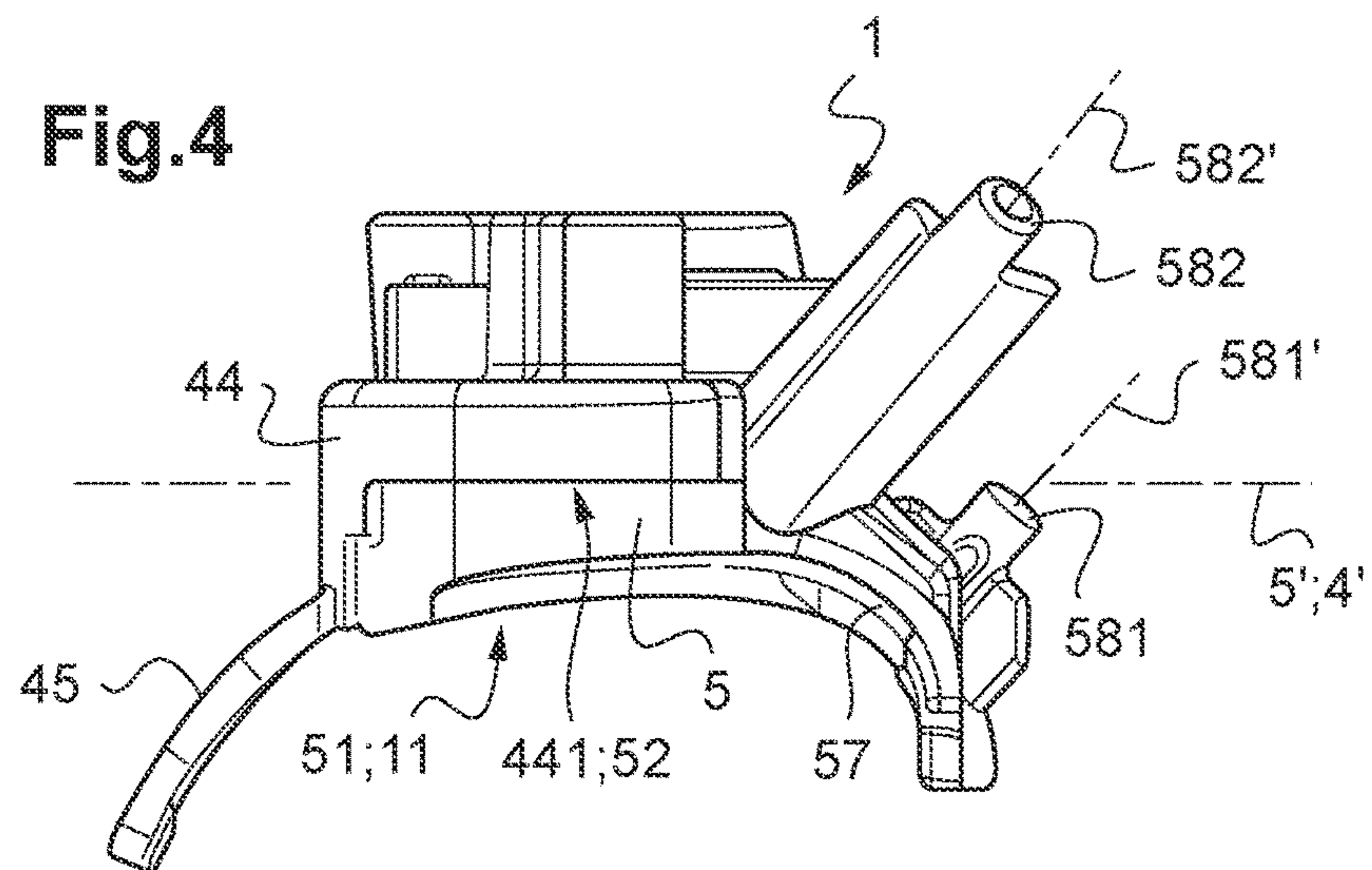


Fig.5

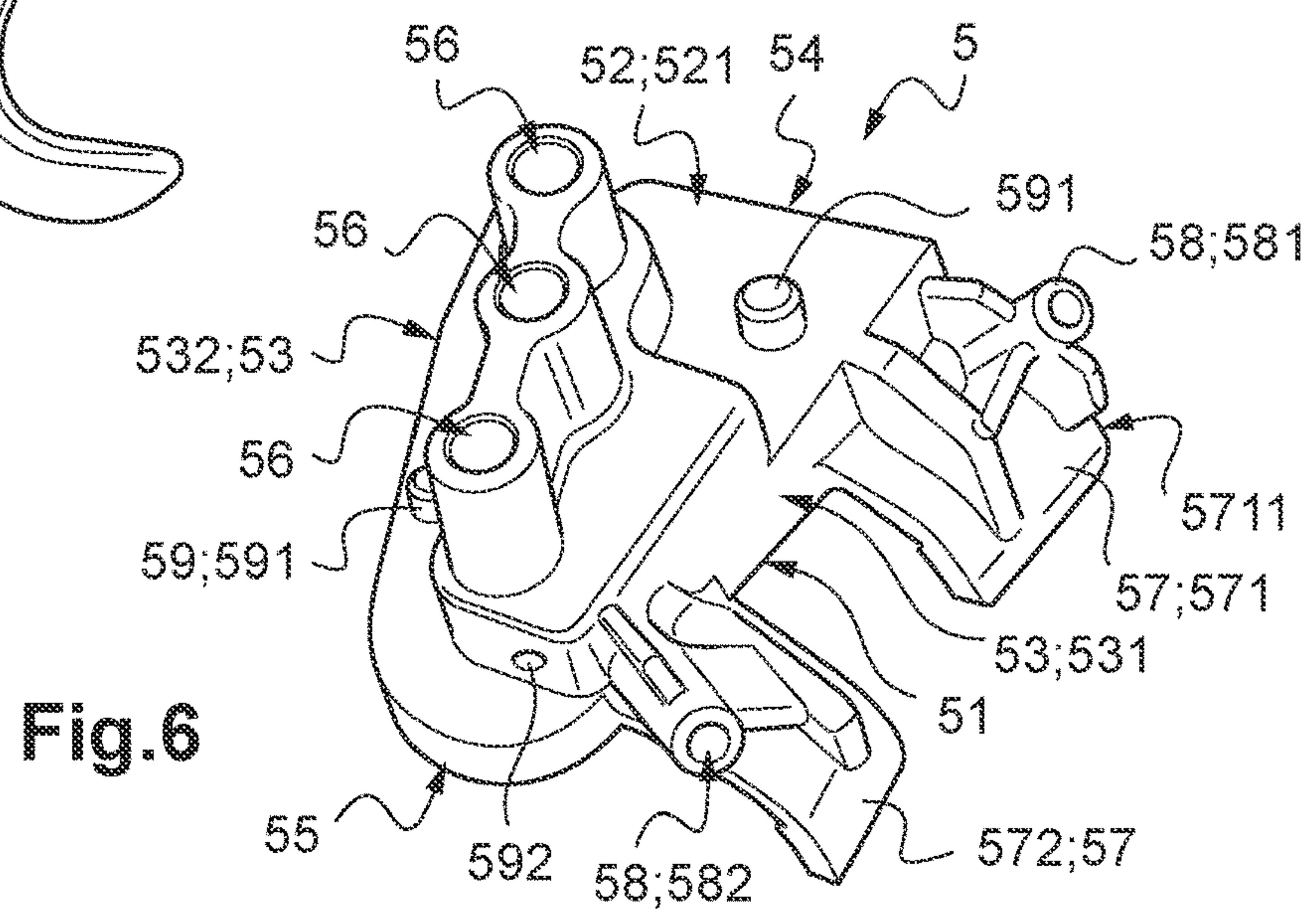
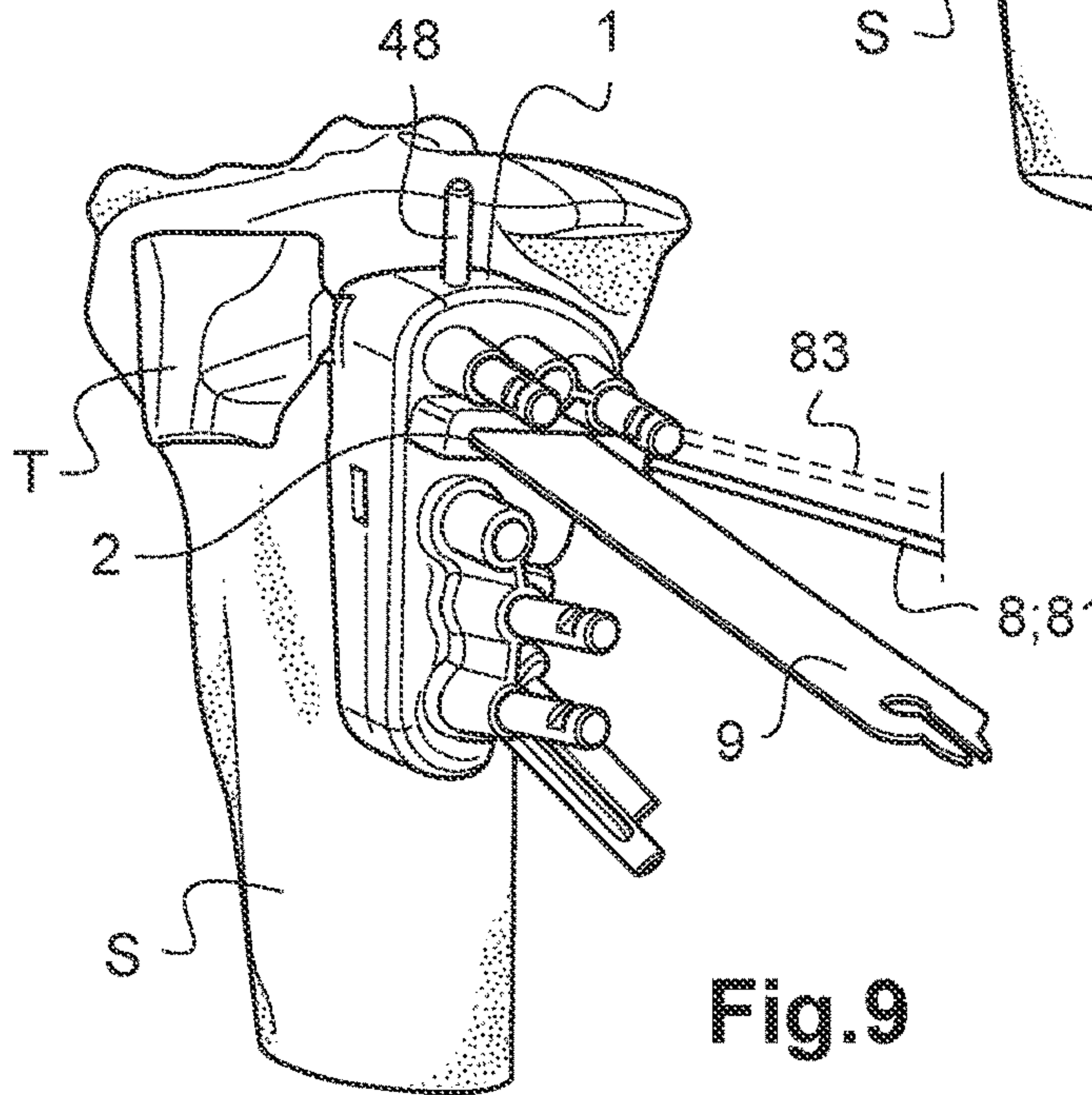
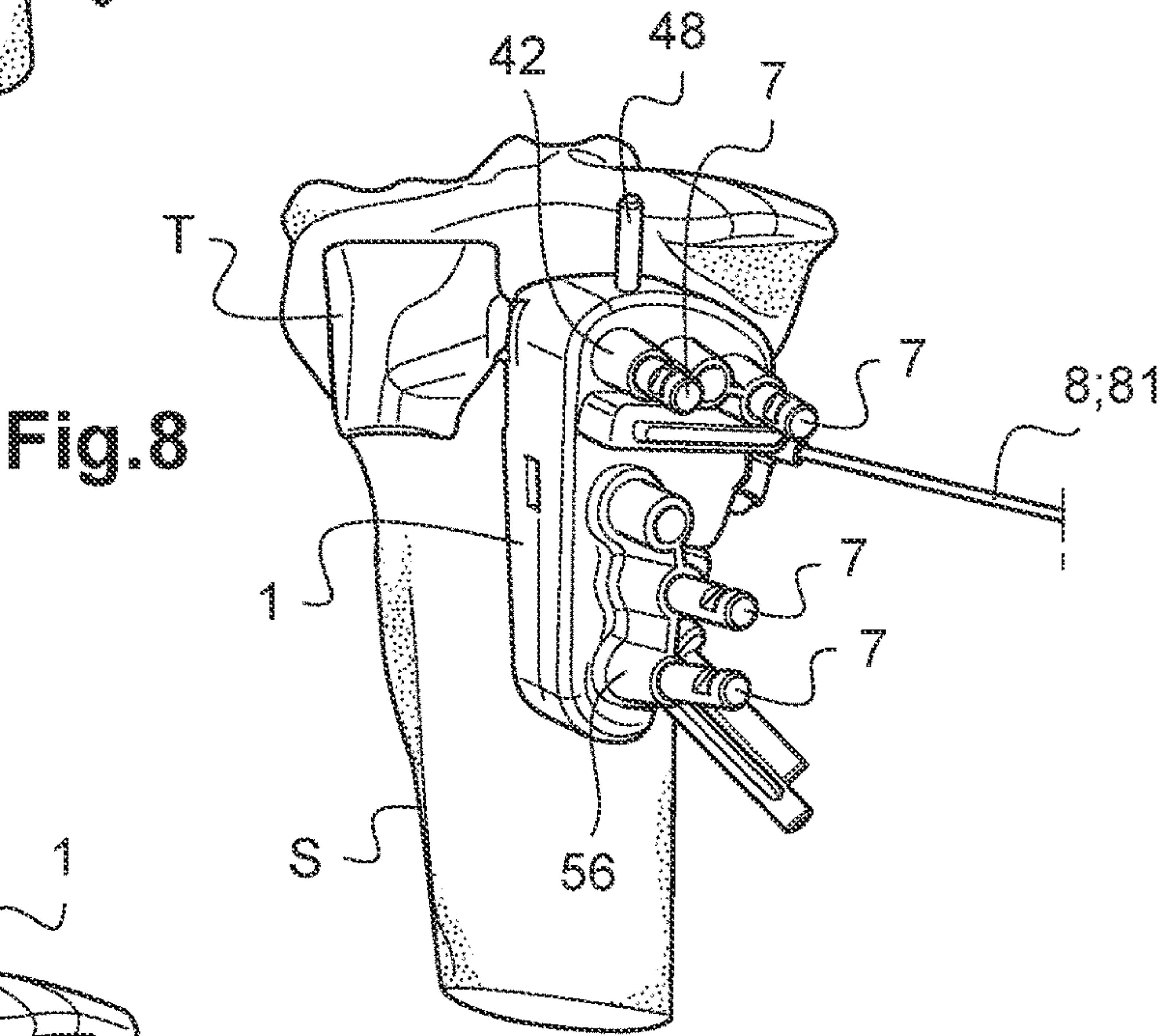
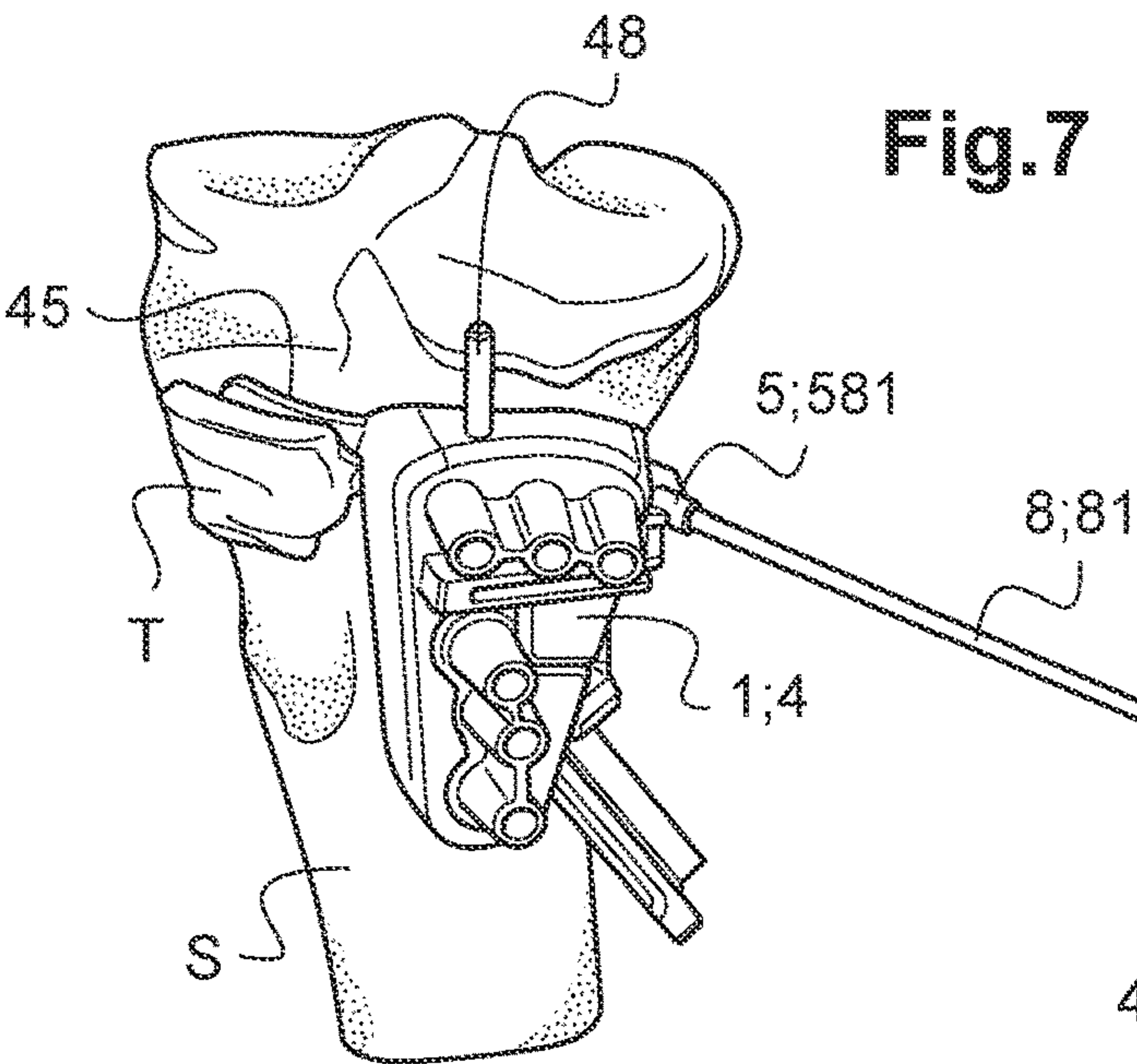
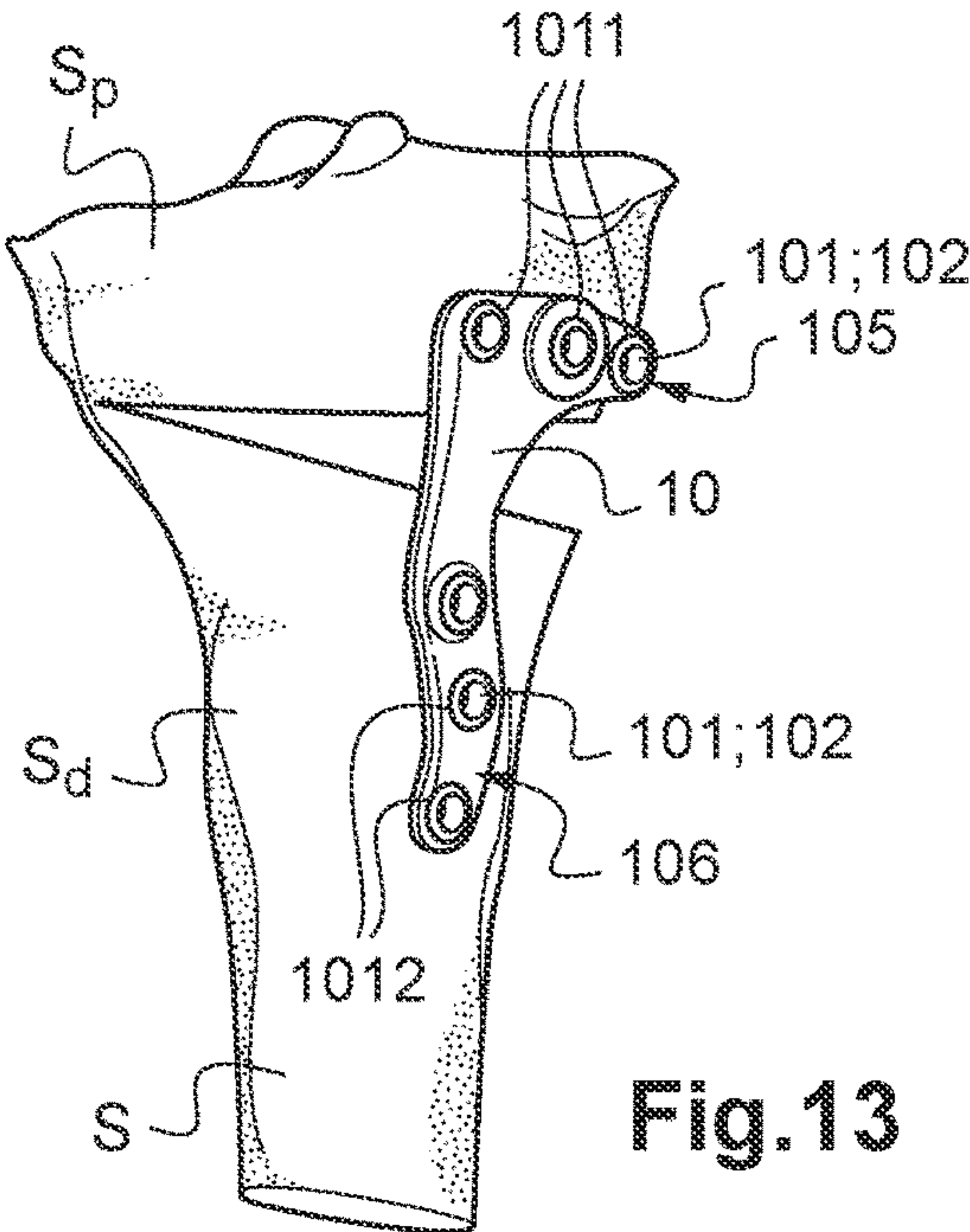
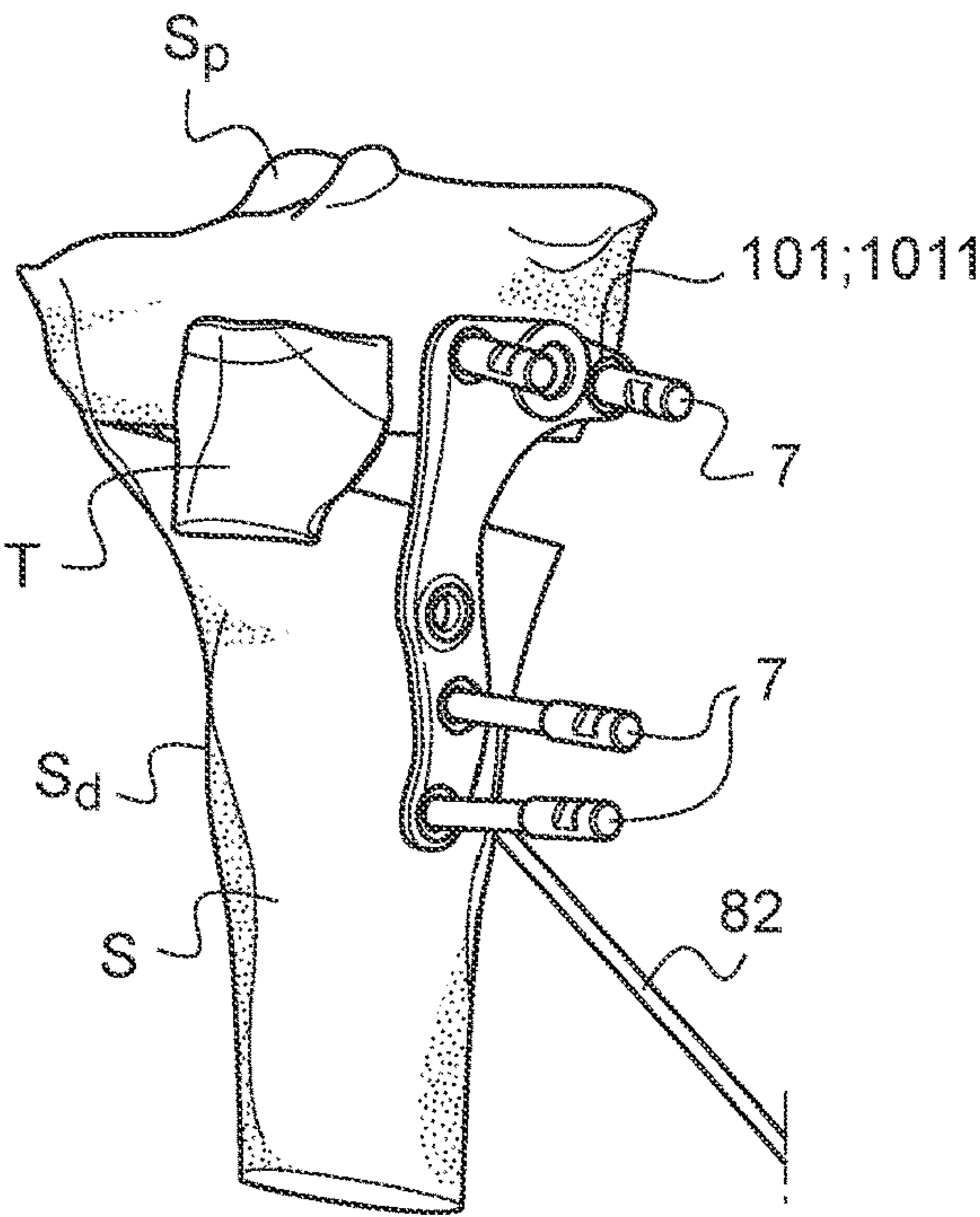
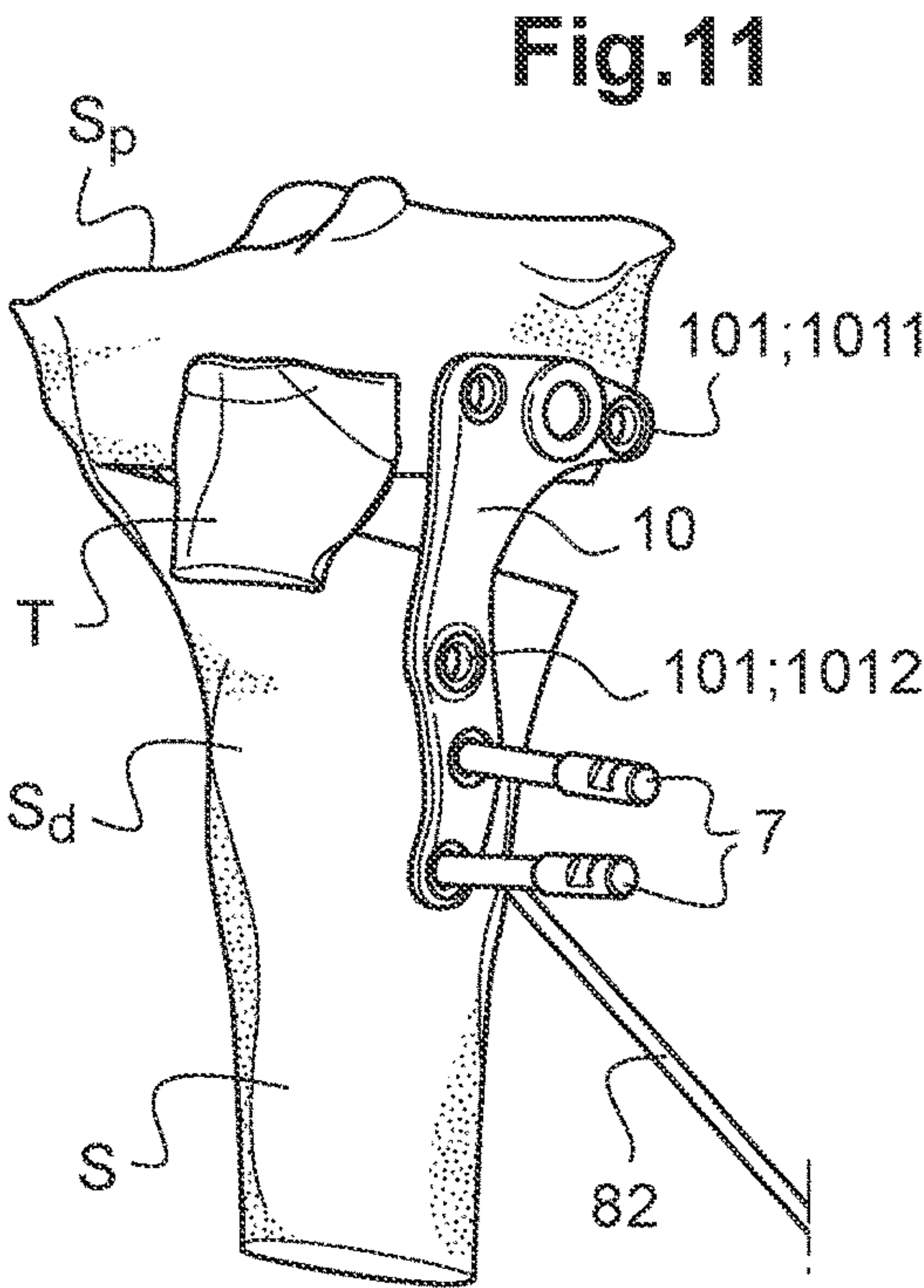
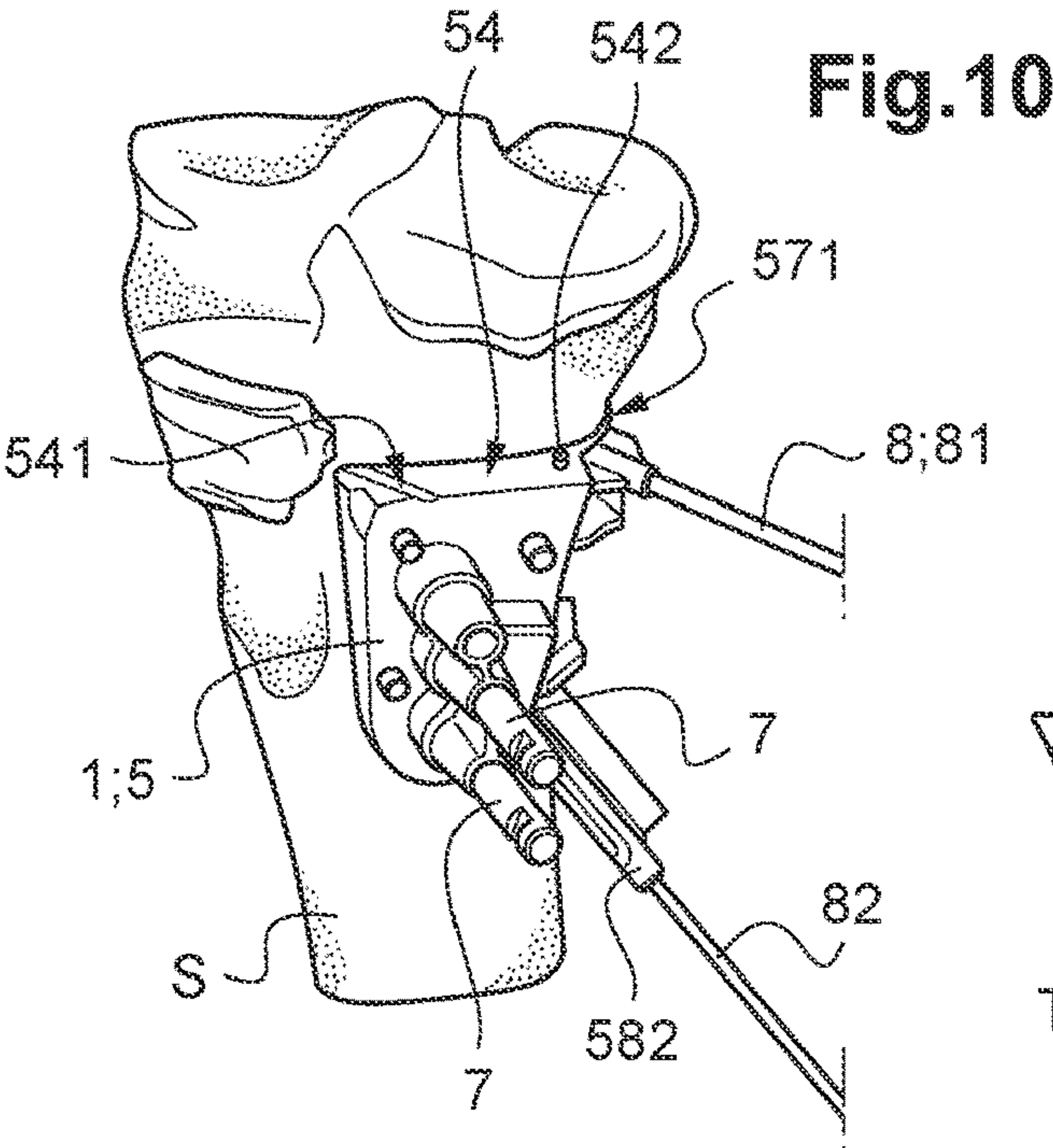
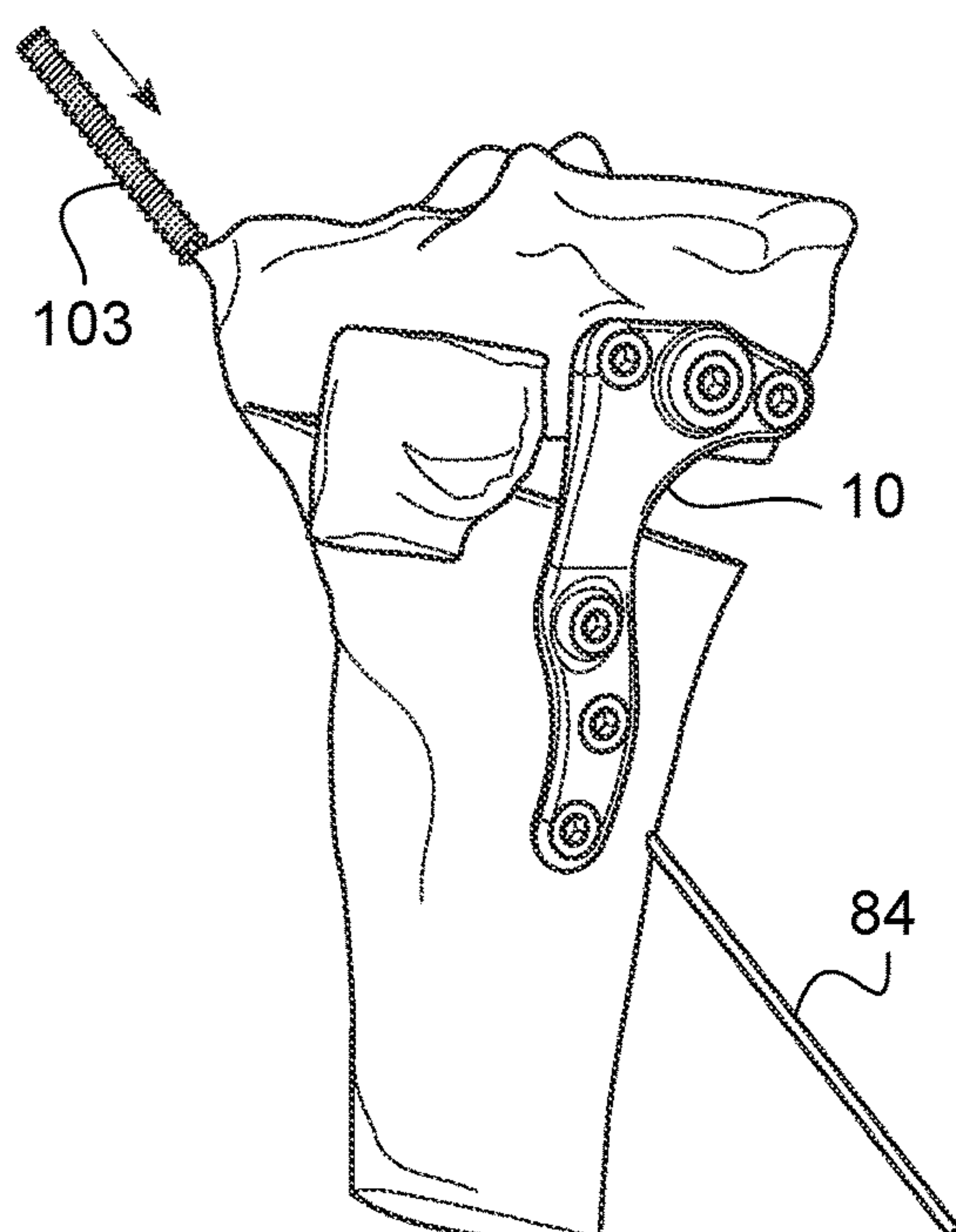
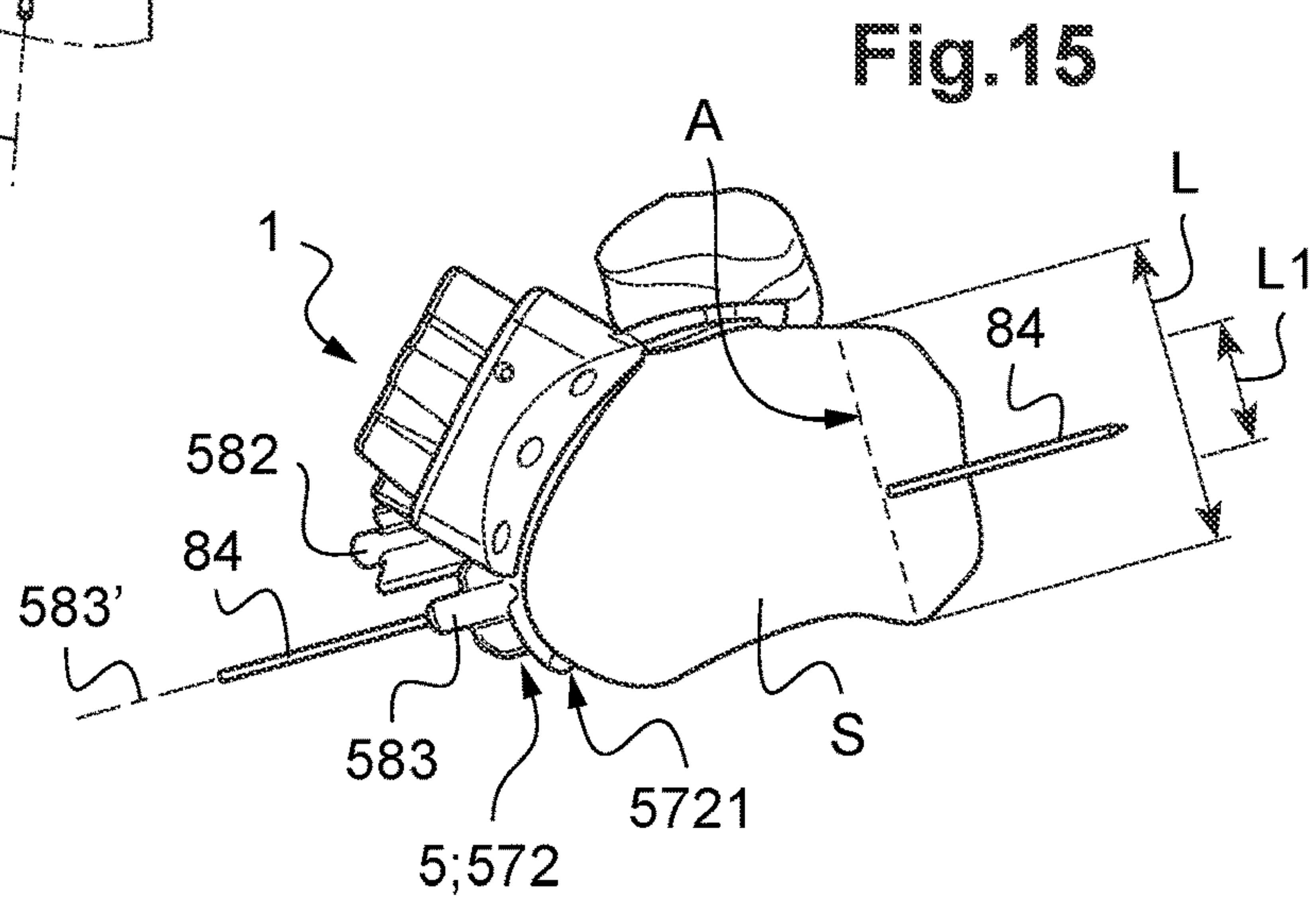
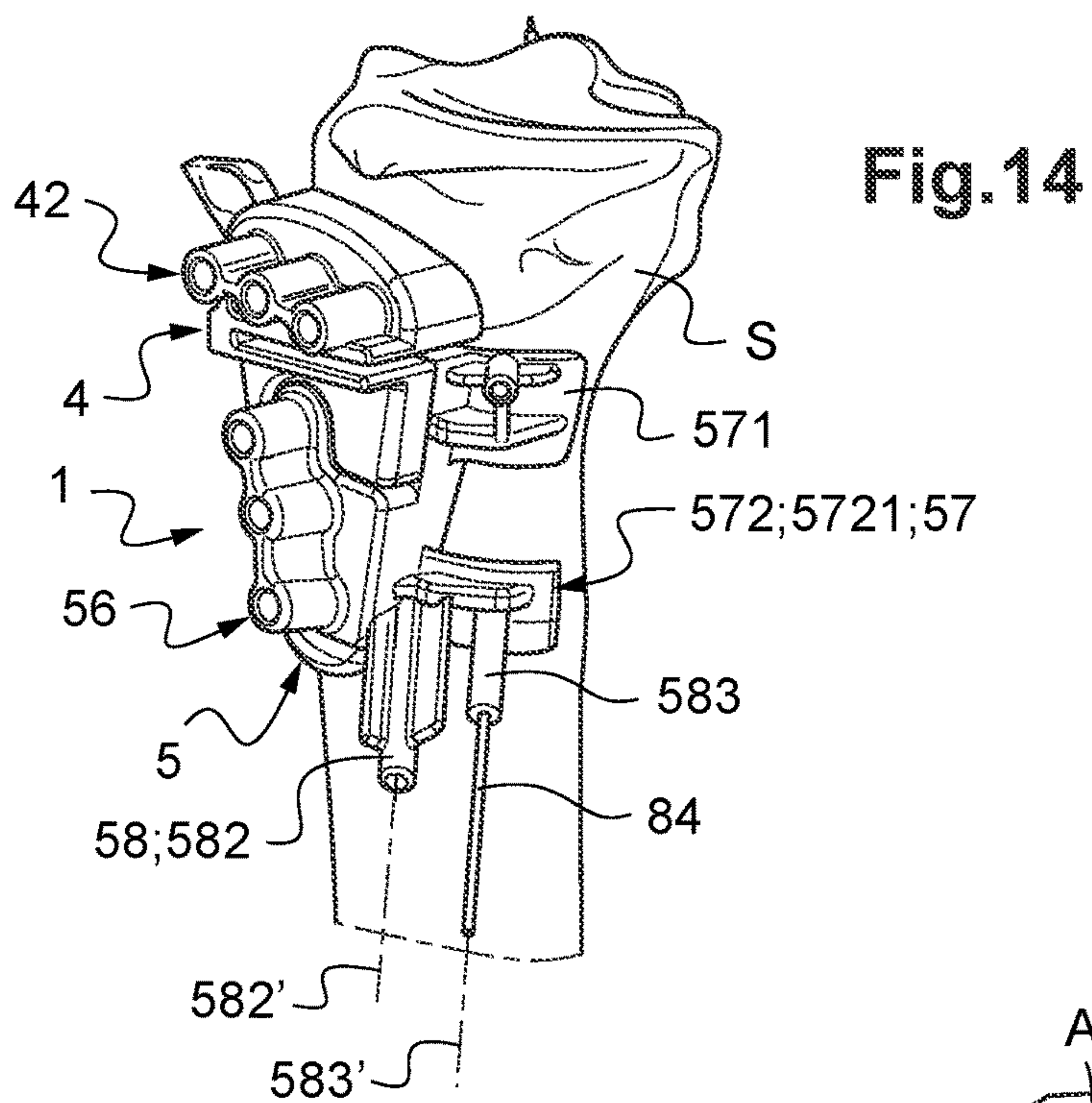


Fig.6







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**SURGICAL METHOD FOR OPENING
WEDGE OSTEOTOMY AND EQUIPMENT
FOR IMPLEMENTING SAME, AND
SURGICAL GUIDE DEVICE AND METHOD
FOR OBTAINING SAME**

CROSS-REFERENCE TO RELATED
APPLICATIONS

This application is a divisional of U.S. patent application Ser. No. 16/640,888 filed on Feb. 21, 2020, which is the U.S. national phase of International Patent Application No. PCT/EP2018/072461 filed on Aug. 20, 2018, which claims priority to FR Patent Application No. 1757798 filed on Aug. 22, 2017, the contents of which are hereby incorporated by reference.

TECHNICAL FIELD TO WHICH THE
INVENTION RELATES

The present invention generally relates to the field of orthopaedic surgery.

It more particularly relates to the surgical devices intended to assist the opening wedge osteotomy techniques.

TECHNOLOGICAL BACK-GROUND

Osteotomy is the surgical cutting of a long bone, to modify the axis, size or shape thereof, for therapeutic or plastic purposes.

Among the osteotomy techniques, the so-called “opening wedge osteotomy” techniques can in particular be mentioned, which consist in cutting the bone to be treated by a cut line, then in spacing apart the edges of the line by introducing therein a wedge made of bone or of an artificial material (metal, cement, bone substitute).

Once the correction obtained, the two bone fragments are firmly maintained by an osteosynthesis material, in particular an osteosynthesis plate held by screws.

Such a surgical operation is for example useful to treat certain arthroses localized at the knee, in order to correct a deformation of the lower limb and to obtain a tibial alignment correction. In particular, the tibial valgus osteotomy remains an operation of choice for treating in internal femorotibial arthritis on a genu varum.

The preoperative planning is essential in this type of operation, in particular to determine accurately the value of the spatial correction that will have to be made through the opening (in particular, HKA angle and tibial slope). But, to date, this planning remains a difficult practice in which operator’s experience and empiricism are of high importance in the success of the operation.

Likewise, during the operation, it is often difficult for the surgeon to scrupulously follow the preoperative planning file, in particular as regards the arrangement of the cut line and of the osteosynthesis plate.

It hence exists a need for means providing assistance to the operator all along the opening wedge osteotomy operation, so as to efficiently follow the preoperative planning.

OBJECT OF THE INVENTION

In order to remedy the above-mentioned drawback of the state of the art, the present invention proposes a surgical guide device, intended to be placed against a patient’s bone, for assisting an opening wedge osteotomy technique.

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This surgical guide device comprises:—a rear face adapted to be positioned against a surface of said bone, and—a window for guiding a cut line intended to be made into said bone.

The guide window is delimited by an upper edge and a lower edge, arranged opposite to each other and spaced apart from each other.

And this surgical guide device comprises two parts that are assembled to each other through detachable fastening means, i.e.:

a proximal part, having a lower edge defining at least one portion of said upper edge of said guide window, and a distal part, having an upper edge defining at least one portion of said lower edge of said guide window.

The proximal and distal parts are each provided with several through-orifices opening through said rear face, adapted to guide a drilling of holes into said bone, and possibly adapted to receive elements temporarily implantable into said bone.

Such a surgical guide device has hence for interest to assist the operator during the opening wedge osteotomy operation, so as to precisely follow the preoperative planning.

As developed hereinafter, the arrangement of the through-orifices of the surgical guide device takes into account the opening wedge osteotomy technique that has been planned and previously simulated via scanner acquisition with a three-dimensional reconstruction of the anatomic region to be corrected.

This approach hence allows anticipating:

the final position of the screw locations in the osteosynthesis plate placed so as to freeze the two bone fragments, and

the spatial position of the bone cut line to be made to generate the desired opening.

The surgical guide device hence advantageously consists of a Patient Specific Instrument (PSI). The design of this instrument uses the imaging technologies and preoperative planning tools for its custom manufacturing, taking into account the unique anatomy of each patient.

This surgical guide device hence helps the surgeon to perform operations in a precise and secure manner.

Other non-limitative and advantageous features of the surgical guide device according to the invention, taken individually or according to all the technically possible combinations, are the following:

the surgical guide device has two lateral edges, at least one of which comprises at least one tab adapted to be positioned against a surface of said bone, wherein said tab has an ability of elastic deformation;

the proximal part comprises at least two through-orifices, juxtaposed and independent of each other, that extend in a virtual strip intended to be directed transversally with respect to the longitudinal axis of the bone;

the proximal part is provided with an upper protrusion, having preferentially the shape of radio-opaque cylindrical dog point, intended to help the practitioner to correctly position the guide at the good distance with respect to the patient’s tibial plateau;

the proximal part also comprises a tubular duct that is adapted to guide the insertion of a rod within the bone, wherein said tubular duct is formed directly overlying the guide window and is directed in such a manner that its longitudinal axis is parallel to the plane of the guide window in order to position a rod helping in the guiding of the cut line;

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the distal part comprises at least two through-orifices, juxtaposed and independent of each other, extending in a virtual strip that is at least approximately perpendicular to the virtual strip followed with the orifices of the proximal part and that is intended to be directed at least approximately parallel to the longitudinal axis of the bone;

the distal part comprises at least one through-orifice in the form of a tubular duct, which is adapted to guide the insertion of a rod within the bone: a proximal tubular duct that is arranged directly underlying the guide window and that is directed in such a manner that its longitudinal axis is parallel to the plane of the guide window in order to position a rod helping in the guiding of the cut line, and/or a distal tubular duct that is arranged remote from the guide window and that is directed in such a manner that its longitudinal axis intersects the plane of the guide window in order to position a cut stop and/or hinge indication rod; according to a particular embodiment, the distal part comprises at least two distal tubular ducts that are arranged remote from the guide window and that are directed in such a manner that their respective longitudinal axes intersect the plane of the guide window in order to each position a cut stop and/or hinge indication rod;

the surgical guide device is made of a plastic material adapted to the additive manufacturing and to an invasive use within the human body.

The invention also proposes equipment for implementing an opening wedge osteotomy technique, that comprises:

a surgical guide device according to the invention, elements temporarily implantable into the bone, through the through-orifices of said surgical guide device, as the case may be, rods temporarily implantable into the bone, through the through-ducts of said surgical guide device,

a cutting blade, for making the cut line guided by the surgical guide device,

an osteosynthesis plate provided with two groups of through-orifices, a proximal one and a distal one, each of said groups of orifices being intended to receive fastening screws intended to be implanted into one of the two bone fragments,

a set of screws for the fastening to the bone, intended to be inserted through the through-orifices of said osteosynthesis plate to fasten the latter to the surface of the bone.

Within this framework, the arrangement of the through-orifices of the proximal part corresponds to the arrangement of the proximal through-orifices of the osteosynthesis plate; and the arrangement of the through-orifices of the distal part corresponds to the arrangement of the distal through-orifices of the osteosynthesis plate.

And the relative arrangement between the two groups of through-orifices of the surgical guide device is function, on the one hand, of the correction intended to be applied during the opening wedge osteotomy technique and, on the other hand, of the relative arrangement of the two groups of through-orifices of the osteosynthesis plate, in order to obtain the desired correction when the orifices formed in the bone come into alignment with those arranged in the plate at the end of the osteotomy site opening process.

The invention also relates to a method for obtaining a surgical guide device according to the invention.

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This method comprises:

a) a step of simulating the correction intended to be applied to a bone by an opening wedge osteotomy technique, from the following data:

anatomic data taken on the bone to be treated, data relating to the osteosynthesis plate to be installed, and

preoperative planning data, relating to the correction intended to be applied to this bone by the opening wedge osteotomy technique, and

b) a step of manufacturing the surgical guide device, taking into account the correction data coming from said simulation step.

According to an advantageous feature, the step of manufacturing said surgical guide device consists of a step of additive manufacturing.

The invention also relates to a computer program comprising program code means recorded on a computer-readable medium, comprising:

first program code means, for loading data relating to the correction intended to be applied to a bone by an opening wedge osteotomy technique, from anatomic data relating to said bone and from data relating to the final position of the screws for fastening the osteosynthesis plate to the bone,

second program code means, for generating manufacturing data relating to the surgical guide device, wherein said manufacturing data contain data relating to the arrangement of the through-orifices of the surgical guide device taking into account said correction data and said screw final position data,

when said computer program is executed by a computer.

The invention also relates to a surgical method of opening wedge osteotomy, wherein said surgical method comprises:

a) a preparation step, during which the surgical guide device is fastened against the surface of the bone, and holes are generated into said bone opposite each of the through-orifices of said surgical guide device (with, possibly, the positioning of at least one lower rod arranged to intersect the hinge of the osteotomy site);

b) a bone osteotomy step, comprising:

a first cutting phase within the guide window of the surgical guide device,

a removal of the proximal part of the surgical guide device, and

a second cutting phase, leaning on the distal part of the surgical guide device;

c) a step of removing the distal part of the surgical guide device;

d) a step of fastening the osteosynthesis plate against a distal fragment of the bone, underlying the cut line, wherein said osteosynthesis plate is arranged so that the through-orifices thereof come opposite holes generated at step a), which are formed in said distal fragment;

e) a step of progressively opening the osteotomy site, until obtaining the desired correction corresponding to a matching of holes generated at step a), which are formed in a proximal fragment of the bone and overlying the cut line, with through-orifices of said osteosynthesis plate; and

f) a step of fastening the osteosynthesis plate against the proximal fragment of the bone.

DETAILED DESCRIPTION OF AN EXEMPLARY EMBODIMENT

The following description with respect to the appended drawings, given by way of non-limitative examples, will

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permit a good understanding of what the invention consists in and of how it can be implemented.

In the appended drawings:

FIG. 1 is an overall and perspective view of a surgical guide device according to the invention, placed against a patient's bone intended to undergo an opening wedge osteotomy technique;

FIG. 2 is a front view of the surgical guide device illustrated in FIG. 1;

FIG. 3 is a perspective view of the surgical guide device illustrated in FIGS. 1 and 2;

FIG. 4 is a bottom view of the surgical guide device of FIGS. 1 to 3.

FIG. 5 is a front view of a proximal part of the surgical guide device of FIGS. 1 to 4, intended to cooperate with a first bone fragment;

FIG. 6 is a perspective view of a distal part of the surgical guide device of FIGS. 1 to 4, intended to cooperate with a second bone fragment;

FIGS. 7 to 13 represent the main steps of implementation of the surgical guide device, within the framework of a surgical operation of opening wedge osteotomy;

FIG. 14 is an overall and perspective view of a second surgical guide device according to the invention, placed against a patient's bone intended to undergo an opening wedge osteotomy technique, that is different from the device illustrated in FIGS. 1 to 13 by the presence of a third tubular duct adapted for guiding a second lower rod;

FIG. 15 is a general top view of the second surgical guide device according to the invention, with a transverse sectional plane passing through the bone and at the future hinge;

FIG. 16 illustrates a step of the surgical method implementing the second surgical guide device, i.e. the guiding of a cannulated screw by the second lower rod, for the insertion thereof into the hinge.

As shown in particular in FIG. 1, the surgical guide device 1 is intended to be placed against a patient's bone S, for assisting the surgeon during an opening wedge osteotomy technique.

By "opening wedge osteotomy", it is meant a surgical operation consisting in cutting a bone of the patient by a cut line, then in spacing apart the edges of the line by introducing therein a wedge made of bone or of an artificial material (metal, cement, bone substitute).

This surgical technique may be used to treat different bones of the human body.

Such a surgical operation is for example useful to treat certain arthroses localized at the knee, in order to correct a deformation of the lower limb and to obtain a tibial alignment correction. In particular, the tibial valgus osteotomy remains an operation of choice for treating in internal femorotibial arthritis on a genu varum.

Generally, the bone S to be treated has a surface S1; and this bone S also has a longitudinal axis S'.

Surgical Guide Device

The surgical guide device 1, shown in more detail in FIGS. 1 to 4, has the general form of a block.

This surgical guide device 1 (also called "guide") comprises a set of faces:

- a rear face 11, adapted to be positioned against a surface S1 of the bone S to be treated,
- a front face 12, located at the opposite of said rear face 11, and
- two lateral faces 13, i.e.: a first lateral face 131 (posterior) and a second lateral face 132 (anterior).

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This surgical guide device 1 also comprises a slot-shaped window 2 for guiding the cut line intended to be made into the bone S.

This guide window 2 is delimited by an upper edge 21 and a lower edge 22, arranged opposite to each other and spaced apart from each other.

These two edges 21 and 22 are rectilinear. They extend parallel to each other, defining together a general plane 2' (FIG. 2).

The distance between the two edges 21, 22 advantageously corresponds to the thickness of the cutting blade (to within the working clearance).

The thickness of the edges 21, 22 (between the rear 11 and front 12 faces) is advantageously comprised between 0.8 mm and 1.6 mm.

The guide window 2 is a through-window, i.e. it opens through the rear 11 and front 12 faces of the surgical guide device 2.

This guide window 2 is moreover laterally open on only one side, at a lateral opening 23 located in the first lateral face 131 of the surgical guide device 1.

The guide window 2 also comprises a lateral edge 24, forming a bottom, that extends between the two edges 21, 22 and that is located opposite the lateral opening 23.

The surgical guide device 1 herein comprises two parts 4, 5 that are assembled to each other by means of removable fastening means.

More precisely, this surgical guide device 1 comprises a first part 4, also called proximal part or portion (FIG. 5), and a second part 5, also called distal part or portion (FIG. 6).

These two parts 4, 5 are intended to each cooperate with one of the two bone fragments intended to be generated by the cut line made into the bone S through the guide window 2.

As described in more detail hereinafter, these two parts 4, 5 are each provided with several through-orifices that are adapted to receive elements temporarily implantable into the bone S and/or to guide a drilling of holes into this bone S.

Each of these parts 4, 5 is advantageously made single-piece in a plastic material adapted to the techniques of additive manufacturing (also called "3D printing" or "three-dimensional printing").

This plastic material is for example chosen among polyamides.

First Part

The first part 4 (proximal part), shown in more detail and in isolation in FIG. 5, comprises an upper portion 41 that has:

- a rear face 411, intended to form an upper portion of the rear face 11 of the surgical guide device 1 (FIG. 3), and
- a front face 412, intended to form an upper portion of the front face 12 of the surgical guide device 1.

The upper portion 41 comprises several through-orifices 42, opening through the rear 411 and front 412 faces thereof.

The through-orifices 42, also called "proximal through-orifices", are adapted to receive elements temporarily implantable into the bone S and/or to guide a drilling of holes into this bone S.

Herein, these through-orifices 42 are intended in particular to serve as a guide for drilling holes into a proximal fragment of the bone in order to facilitate the latter assembly of the osteosynthesis plate.

The juxtaposed through-orifices 42 are at least two in number (herein, three in number).

These through-orifices 42 extend in a virtual strip 42' intended to be directed transversally to the longitudinal axis S' of the bone S (FIG. 1).

This upper portion **41** comprises a lower edge **413**, intended to form the upper edge **21** of the guide window **2**.

This upper portion **41** is also delimited by two lateral edges **414** forming an upper portion of the lateral faces **13** of the surgical guide device **1**.

One of these lateral edges **414** herein comprises a lateral tab **45** (anterior tab) that is adapted to be positioned against a surface of the bone **S**, as developed herein in relation with FIGS. **7** to **13**.

The tab **45** has an ability of elastic deformation, so as to optimally conforms the surface of the bone **S**.

This tab **45** extends approximately parallel to the lower edge **413** and on the side of the rear face **411** of the upper portion **41** (FIG. **4**). Its rear face approximately corresponds to the anatomic surface of the bone intended to be covered by it.

The upper portion **41** is herein extended by a lower portion **44** that is intended to cooperate with the second part **5**, for the detachable assembly thereof.

The lower portion **44** is in the general form of a platen intended to conform a complementary recess formed in the front face of the second part **5**.

This lower portion **44** then comprises:

- a rear face **441**, intended to cover the second part **5** of the surgical guide device **1** (FIG. **3**), and
- a front face **442**, intended to form a portion of the front face **12** of the surgical guide device **1**.

The rear face **441** of the lower portion **44** is set back with respect to the rear face **411** of the upper portion **41**.

This lower portion **44** is herein also delimited by an upper edge **443** that is intended to form a portion of the lower edge **22** and the lateral edge **24** of the guide window **2**, in particular intended to form the front portion of this lower edge **22**.

This lower portion **44** also comprises an aperture **444**, within which a complementary shape of the second part **5**, in particular a portion comprising the through-orifices of this second part **5**, are intended to be seated.

The proximal part **4** is also provided with an upper protrusion **48** that is intended to help the practitioner to correctly position the surgical guide device **1** at the good distance with respect to the patient's tibial plateau (checking of the guide **1** altitude).

This upper protrusion **48** is placed, herein removably, at an upper (free) face **418** of the upper portion **41**.

This upper protrusion **48** has preferentially the shape of a radio-opaque cylindrical dog point (also called stem or rod).

Moreover, optionally, this first part **4** also comprises a tubular duct **49** adapted for receiving an additional rod intended to be temporarily implanted into the bone **S** for assisting the osteosynthesis technique (this tubular duct **49** is shown in dotted lines in FIGS. **2**, **3** and **5**).

This tubular duct **49** is herein arranged in the upper portion **41**, through the other lateral edge **414** thereof and near the lower edge **413** thereof (intended to form the upper edge **21** of the guide window **2**).

This tubular duct **49** has a longitudinal axis **49'** that is directed parallel, or at least approximately parallel, to the above-mentioned lower edge **413** (FIG. **2**).

This tubular duct **49** is hence directly arranged overlying the guide window **2** and is directed in such a manner that its longitudinal axis **49'** is parallel to the plane **2'** of the guide window **2** to position a rod helping in the guiding of the cut line (this "additional" rod **83** is schematically shown in FIG. **9**).

This tubular duct **49** extends parallel to the plane defined by the upper edge **21** of the guide window **2**, with an offset

comprised between 0.5 and 3 mm with respect to this upper edge **21** (preferably of the order of 1 mm).

This tubular duct **49** also defines an angle comprised between 10° and 30° with respect to the general plane of the first part **4'** (FIG. **4**).

Second Part

The second part **5**, illustrated in isolation in FIG. **6**, also comprises several faces:

two opposite faces: a rear face **51** and a front face **52**,
two lateral faces **53**: a first lateral face **531** (on the right in FIG. **6**) and a second lateral face **531** (on the left in FIG. **6**), forming a lower portion of the lateral faces **13** of the surgical guide device **1**, and

two end faces: a proximal face **54** and a distal end **55**.

The rear face **51** is intended to form a lower portion of the rear face **11** of the surgical guide device **1** (FIG. **3**).

The front face **52** comprises a recess **521** intended to receive the lower portion **44** of the first part **4**.

The proximal face **54** constitutes an upper edge of the second part **5**, which is intended to form a portion of the lower edge **22** of the guide window **2** (herein a rear portion of this lower edge **22**) herein in combination with the upper edge **443** of the lower portion **44** of the first part **4**.

A location **541** dedicated to the guidance of a biplanar cutting may be provided at this proximal face **54** (visible in FIG. **10**).

This location **541** is added to the surgical guide device **1** when the cut line comes into conflict with the tibial tuberosity. It is then necessary to protect the insertion of the patellar tendon by this method.

This location **541** is herein located on the opposite side with respect to the lateral opening **23**.

This proximal face **54** also comprises, on the side of the lateral opening **23**, spacer means **542** to maintain the spacing between the two edges **21**, **22** of the guide window **2** (FIGS. **2** and **10**).

These spacer means **542** consist for example of an integral stud equipping the proximal face **54** and coming into rest against the lower edge **413** of the first part **4**.

The second part **5** comprises several through-orifices **56** that are adapted to receive elements temporarily implantable into the bone **S** and/or to guide a drilling of holes into this bone **S**.

Herein, this second part **5** comprises through-orifices **56**, also called "distal through-orifices", which are intended in particular to serve as a guide for the drilling of holes into a distal fragment of the bone in order to facilitate the later assembly of the osteosynthesis plate.

These through-orifices **56** open through said rear **51** and front **52** faces of the second part **5**.

These juxtaposed through-orifices **56** are at least two in number (herein three in number).

These through-orifices **56** extending in a virtual strip **56'** intended to be directed approximately parallel with respect to the longitudinal axis **S'** of the bone (FIG. **1**).

The first lateral face **531** of this second part **5** comprises tabs **57** intended to be positioned against the surface of the bone **S**, as developed hereinafter in relation with FIGS. **7** to **13**.

These tabs **57** have a rear face that corresponds approximately to the anatomic surface of the bone intended to be covered by them; they have an ability of elastic deformation, so as to conform optimally the surface of the bone **S**.

These tabs **57** extend approximately parallel to the proximal face **54** and on the side of the rear face **51**.

Herein, this second part **5** comprises two tabs:

an upper tab **571**, arranged along the proximal face **54**,
and

a lower tab **572**, arranged on the side of the distal face **55**.

In particular, the upper tab **571** comprises an upper edge **5711** extending in the continuation of the proximal face **54** so as to help in forming the guide surface for the cut line.

Moreover, this second part **5** also comprises tubular ducts **58** adapted to receive rods intended to be temporarily implanted into the bone **S** for assisting the osteosynthesis technique.

A first, upper or proximal, tubular duct **581** (also called “upper barrel”) is herein arranged through the upper tab **571**.

This upper tubular duct **581** comprises a longitudinal axis **581'** that is directed parallel, or at least approximately parallel, to the proximal face **54** (FIG. 2).

This longitudinal axis **581'** is moreover advantageously directed parallel, or at least approximately parallel, to the longitudinal axis **49'** of the tubular duct **49** of the first part **4**.

This proximal tubular duct **581** is arranged directly underlying the guide window **2** and is directed in such a manner that its longitudinal axis **581'** is parallel to the plane **2'** of the guide window **2**.

This proximal tubular duct **581** is adapted to guide an upper rod that is intended to help in guiding the cut line.

This proximal tubular duct **581** extends parallel to the plane defined by the lower edge **22** of the guiding window **2**, with an offset comprised between 0.5 and 3 mm with respect to this lower edge **22** (preferably of the order of 1 mm).

This proximal tubular duct **581** also defines an angle comprised between 10° and 30° with respect to the general plane of the second part **5'** (FIG. 4).

A second, lower or distal, tubular duct **582** (also called “lower barrel” or “first distal tubular duct” or “first lower tubular duct”) is arranged through the lower tab **572**.

This lower tubular duct **582** is directed in such a manner that its longitudinal axis **582'** intersects the general plane **2'** of the guide window **2** (FIG. 2).

This intersection point is intended to be located in the bulk of the bone, in particular at the opening site.

The intersection point makes it possible to localize a theoretical point located at a determined distance from the bone surface and from the plateau (for example, the theoretical point is located 10 to 11 mm from the external cortex).

This lower tubular duct **582** is intended to guide an ascending, lower rod serving as a cut stop and/or a hinge indication.

The direction of the longitudinal axis **582'** of this lower tubular duct **582** may be defined by two angles:

a first angle of inclination defined between the longitudinal axis **582'** and the general plane **2'** of the guide window **2**, comprised between 40° and 70° (FIG. 2),
and

a second angle of inclination defined between the longitudinal axis **582'** and the general plane of this second part **5'**, comprised between 35° and 70° (FIG. 4).

FIGS. 14 and 15 show a second surgical guide device according to the invention, that is a variant of the surgical device described hereinabove in relation with FIGS. 1 to 6.

The second surgical guide device **1** is different only by the presence of a third tubular duct **583** (also called “second lower tubular duct” or “second distal tubular duct”),

arranged in the second part **5** for receiving a rod intended to be temporary implanted into the bone **S** for assisting the osteosynthesis technique.

The third, also lower or distal, tubular duct **583** (also called “second lower barrel”) is herein arranged through the lower tab **572**.

This third tubular duct **583** is herein arranged between the second tubular duct **582** and the free end **5721** of this lower tab **572**. As an alternative, not shown, as a function of the primary location of the second tubular duct **582**, the third tubular duct **583** can also be arranged between the first lateral face **531** of the second part **5** and the second tubular duct **582**; this is for example the case when this second tubular duct **582** is offset and decentred to take into account the required change of tibial slope (indeed, the more we open posteriorward, the more the first rod will go anteriorward and hence close to the free end **5721** of the lower tab **572**).

This third tubular duct **583** is oriented to that its longitudinal axis **583'** intersects the general plane **2'** of the guide window **2** (FIG. 2).

Its intersection point is intended to be located in the bulk of the bone, in particular at the opening site and still more precisely at the hinge.

The intersection point makes it possible to localize a theoretical point located at a determined distance from the bone surface and from the plateau (for example, the theoretical point is located 10 to 11 mm from the external cortex).

This third tubular duct **583** is intended to guide a second, ascending, lower rod. As illustrated in FIG. 16, the second lower rod is also useful to guide the insertion of a cannulated screw through the hinge.

The direction of the longitudinal axis **583'** of this third tubular duct **583** is advantageously parallel to the longitudinal axis **582'** of the second tubular duct **582**.

Detachable Fastening Means

The two parts **4**, **5** are assembled to each other through detachable fastening means **59**, herein in the form of complementary fitting structures.

For that purpose, at its recess **521**, the front face **51** of the second part **5** comprises dog points **591** (FIG. 6) intended to cooperate by fitting with complementary mortises (not visible) that are arranged at the rear face **441** of the distal portion **44** of the first part **4**.

The second part **5** is also provided with lugs **592**, for example in the form of spherical caps or conical studs (FIG. 6), which are judiciously distributed so as to cooperate by elastic fitting with complementary housings (not visible) equipping the first part **4**.

Herein, these complementary lugs and housings are arranged on the opposite edges, on the one hand, of the aperture **444** of the first part **4** and, on the other hand, of the recess **521** of the second part **5**.

Equipment for Opening Wedge Osteotomy Technique

As shown in FIG. 7 and following, the surgical guide device **1** is intended to be used in combination with a set of other elements for the implementation of the opening wedge osteotomy technique.

The corresponding equipment hence advantageously comprises:

elements temporarily implantable into the bone, through the through-orifices **42**, **56** of this surgical guide device **1**, i.e. in particular rigid axes **7** (called “pins”),
rods **8** temporarily implantable into the bone **S**, through the through-ducts **49**, **58** of said surgical guide device **1**,

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a cutting blade **9** (FIG. **9**), associated with a surgical motor, to perform the cut line guided by the surgical guide device **1**,

an osteosynthesis plate **10** (FIGS. **11** to **13**), provided with through-orifices **101** for receiving fastening screws **102** intended to be implanted into the bone S, and

a set of screws **102** for the fastening to the bone S, intended to be inserted into the through-orifices **101** of the osteosynthesis plate **10** to fasten the latter to the surface of the bone S.

The osteosynthesis plate **10** is intended to be fastened to the two bone fragments, after the opening wedge osteotomy technique guided by the surgical guide device **1**, so as to freeze the correction brought by the surgeon.

Such an osteosynthesis plate **10** is for example described in detail in the document FR2980967.

As described hereinafter in relation with FIG. **13**, this osteosynthesis plate **10** is composed of two elongated portions, herein having together a general L-shape, i.e.:

a proximal part **105**, intended to be positioned against a proximal fragment Sp of the bone S, and

a distal part **106**, intended to be positioned against a distal fragment Sd of this same bone S.

Each of these two parts **105**, **106** is provided with a group of through-orifices **1011**, **1012** for receiving fastening screws **102**.

According to the invention, the arrangement of each group of through-orifices **42**, **56** of the surgical guide device **1** corresponds to the arrangement of one the two groups of through-orifices **1011**, **1012** of the osteosynthesis plate **1**:

the arrangement of the through-orifices **42** of the first part **4** corresponds to the arrangement of the through-orifices **1011** of the proximal part **105** of the osteosynthesis plate **10**, and

the arrangement of the through-orifices **56** of the second part **5** corresponds to the arrangement of the through-orifices **1012** of the distal part **106** of the osteosynthesis plate **10**.

Still according to the invention, the relative arrangement between the two groups of through-orifices **42**, **56** of the surgical guide device **1** is function, on the one hand, of the correction intended to be applied during the opening wedge osteotomy technique and, on the other hand, of the relative arrangement of the two groups of through-orifices **1011**, **1012** of the osteosynthesis plate **1**.

Manufacturing of the Surgical Guide Device

The manufacturing of the surgical guide device **1** is advantageously custom made for the patient. This surgical guide device **1** hence advantageously consists of a patient specific instrument or "PSI".

The manufacturing of this surgical guide device **1**, and as a corollary of its two constituent parts **4**, **5**, advantageously takes into account the following data:

anatomic data taken on the bone to be treated, advantageously obtained by a medical imaging technique (for example, scanner),

data relating to the osteosynthesis plate **10** to be installed, in particular the final position of the locations of the screws **102** for the fastening of the osteosynthesis plate **10**, and

preoperative planning data, relating to the correction intended to be applied to this bone by the opening wedge osteotomy technique.

The method for obtaining a surgical guide device **1** according to the invention advantageously comprises the following steps:

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a/ a step of simulating the correction intended to be applied to the bone S by an opening wedge osteotomy technique from the above-mentioned data, then

b/ a step of manufacturing as such the surgical guide device **1**, taking into account the correction data coming from the simulation step.

For the implementation of the simulation step, the invention advantageously proposes a preoperative planning tool in the form of a computer program intended to generate data for the manufacturing of the surgical guide device **1** on the basis of the above-mentioned data.

Herein, this computer program comprises program code means recorded on a computer-readable medium, comprising:

first program code means, for loading data relating to the correction intended to be applied to a bone by an opening wedge osteotomy technique, from anatomic data relating to the bone to be treated and from data relating to the final position of the screws for fastening the osteosynthesis plate to the bone, and

second program code means, for generating manufacturing data relating to the surgical guide device **1**, wherein said manufacturing data contain data relating, on the one hand, to the shape of the rear face **11** of the surgical guide device **1** and, on the other hand, to the arrangement of the through-orifices **42**, **56** of the surgical guide device **1** taking into account said correction data and said screw final position data,

when said computer program is executed by a computer.

The anatomic data of the bone to be treated consist for example of data coming from a scanner acquisition, from which a three-dimensional modelling of all the parts involved in the correction process is performed.

The correction data are provided by the surgeon, within the framework of its preoperative planning.

The final position of the screws and of the plate itself respects the common principles required for obtaining the mechanical performance sought for this material (in particular the anatomic positioning of the implant).

The second program code means advantageously consist of three-dimensional modelling means that are intended to generate the manufacturing data relating to the surgical guide device **1** as a "three-dimensional file" (or "3D file") that corresponds to a three-dimensional model operable by a three-dimensional printer.

As illustrated in relation with FIG. **7** and following, in said manufacturing data, the arrangement of the through-orifices **42**, **56** of the surgical guide device **1** takes into account the planned opening wedge osteotomy technique and anticipates the final position of the screw locations in the osteosynthesis plate **10** placed so as to freeze the two bone fragments Sp and Sd.

The step of manufacturing the surgical guide device **1** consists of a step of additive manufacturing.

Surgical Method of Opening Wedge Osteotomy

A first step of the surgical method consists of a preparation step (FIGS. **7** and **8**).

During said preparation step, the surgical guide device **1** (with its two parts **4** and **5** assembled to each other) is positioned so that the rear face **11** thereof comes into rest on the surface of the bone S, at the position of the future location of the osteosynthesis plate **10**.

In the case of an internal tibial valgus opening wedge osteotomy, the surgical guide device **1** is positioned at the antero-internal part of the tibia.

In this case, as shown in FIG. **7**, the tab **45** of the first part **4** then comes into rest on the insertion of the patellar tendon

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T, at the anterior tibial tuberosity; the tabs **57** of the second part **5** allow a good flattening of the surgical guide device **1** to the bone and a clearance compensation, so that the above-mentioned tab **45** is efficiently flattened to the posterior face of the patellar tendon T (position adjustment perpendicular to the axis S' of the bone S).

The upper protrusion **48** (located at the top of the surgical guide device **1**) allows a first visual adjustment in height of the surgical guide device **1** (checking of the guide **1** altitude).

Finally, the upper rod **81** (or even the additional rod **83**) makes it possible to control and validate this good positioning of the surgical guide device **1** thanks to a visualization with an image intensifier.

The upper rod **81**, inserted into the second part **5** of the surgical guide device **1** and into the bone S through the upper tubular duct **581**, temporarily freezes the surgical guide device **1** on the bone.

Optionally, the additional rod **83**, inserted into the first part **4** of the surgical guide device **1** and into the bone S through the dedicated tubular duct **49**, also helps in temporarily freezing the surgical guide device **1** on the bone.

This upper rod **81** (or even also the additional rod **83**) also allows a checking of the altitude of the surgical guide device **1**, in accordance with the planning file. For that purpose, the trajectory of this radio-opaque upper rod **81** (or even also of the additional rod **83**) is superimposed to the theoretical trajectory determined during the simulation, such information appearing in the operative planning file provided to the surgeon.

The preparation step also comprises a "drilling" step, i.e. a step of forming holes into the bone S opposite each of the through-orifices **42**, **56** of the surgical guide device **1**.

For example, the holes are blind-holes at the (proximal) through-orifices **42** of the first part **4** and, on the other hand, are through-holes (bicortical) at the (distal) through-orifices **56** of the second part **5**, respectively.

This surgical guide device **1** is then temporarily fastened against the surface of the bone S, by means of pins **7** placed through some at least of the through-orifices **42**, **56** (FIG. **8**).

This temporary fastening allows a robust holding of the surgical guide device **1** in order to ensure a very precise cutting within the guide window **2**.

When this preparation step is finished, a step of osteotomy of the bone may be performed.

The beginning of the cutting is made thanks to the guide window **2**, custom-positioned and dedicated to the previously known thickness of the cutting blade **9** (FIG. **9**).

The upper rod **81** (or even also the additional rod **83**) moreover allows following the trajectory of the cutting blade **9**. This upper rod **81** (or even also the additional rod **83**) allows visually checking that the good direction of cutting is not lost (for example, if the adjustment between the thickness of the blade and that of the window is too wide).

A lower rod **82** (also called "first lower rod **82**") is then inserted into the bone, guided by the lower tubular duct **582** (FIG. **10**).

This lower rod **82** is arranged so as to intersect the hinge of the osteotomy site (the site represents the empty space that will be created upon the tibia opening made possible by the saw line). In other words, this lower rod **82** intersects an axis of rotation A (FIG. **15**), extending from the posterior part to the anterior part of the tibia, which represents the base line of the rotation about which the opening is made; this lower rod **82** further advantageously extends perpendicular, or at least approximately perpendicular, to this axis of rotation A.

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This arrangement also provides a protection of the hinge during the opening movement, serving as a deformation "guide" and avoiding any breaking.

It also forms a cut stop but also the indication of the ideal position for the hinge.

According to the second embodiment, a second lower rod **84** may be inserted into the bone, guided by the third tubular duct **583** (FIGS. **14** to **16**).

This second lower rod **84** is also arranged so as to intersect the hinge of the osteotomy site, near the intersection point of the first lower rod **82**. In other words, here again, this second lower rod **84** intersects the axis of rotation A (FIG. **15**) that represents the base line of the rotation about which the opening is made; this second lower rod **84** further advantageously extends perpendicular, or at least approximately perpendicular, to this axis of rotation A.

On this matter, this second lower rod **84** is advantageously strictly parallel to the first lower rod **82**. This arrangement allows the second lower rod **84** to cross the axis of rotation of the hinge exactly in the same conditions as the first lower rod **82**.

Preferably, the intersection point of the second lower rod **84** within the hinge is in a central portion L1 of the length L of this hinge (FIG. **15**).

Such an arrangement aims at balancing, in the depth of the front plane, the location of the second lower rod **84** so that the screw slides on the latter and rebalances the fastening forces in case of breaking of the hinge.

For example, this central portion L1 (centred along the length of the hinge L) has a length corresponding to $\frac{1}{3}$ (or even $\frac{1}{4}$, possibly $\frac{1}{5}$) of the length of said hinge.

In a variant embodiment, the first lower rod **82** may be centred along the length of the hinge. In this case, the second lower rod **84** is offset along the length of this hinge, while remaining the closest possible of this first lower rod **82**.

In practice, the second lower rod **84** is inserted after the cutting is finished. It may also be useful to recover the integrity of the hinge if the latter should break despite the presence of the first lower rod **82**.

Moreover, the presence and visualization thereof beyond the cutting and beyond the lateral cortex makes it possible, if necessary, to come through external path, to thread the cannulated screw and to reinforce/synthesize the external hinge.

The first part **4** can then be removed after extraction of the holding pins **7** (FIG. **10**).

The cutting blade **9** will be able to bear against the distal part **5** still fastened to the bone, and in particular to the upper tab **571** thereof, in order to continue following the ideal trajectory.

The operator can then get the hinge point by mechanically abutting against the first lower rod **82** that extends at the osteotomy site.

The hinge between the two bone fragments Sp, Sd is hence protected by this first lower rod **82** (or even also by the second lower rod **84**) that passes through the cut line.

The first lower rod **82** (or even also the second lower rod **84**) is left until the end of the operation when the plate is fully integral with the bone. Hence, all the intermediate handlings traumatizing the hinge, and that would risk to fragilize (or even break) it, are preserved thanks to the constant presence of this first lower rod **82** (or even also of the second lower rod **84**).

It is to be noted that, once the second (distal) part **5** removed, it may slide along this first lower rod **82** (or even also the second lower rod **84**) so that the (these) latter remain in position. The first lower rod **82** (or even also the second

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lower rod **84**) hence plays a role of “stress absorber” and protects the bone from a risk of fracture, liable to create the separation of the two bone fragments.

Once the cut line ended, the second part **5** is also removed, while keeping the lower rod **82** (or even also the second lower rod **84**) in unchanged position.

The osteosynthesis plate **10** is positioned by reinserting the pins **7** through the distal through-orifices **1012** thereof and so that they enter the holes of the distal fragment Sd obtained thanks to the second part **5** (FIG. **11**).

The bone opening movement is performed by the operator. This operating movement is for example performed by means of a wedge inserted between the two bone fragments Sp and Sd (or any other suitable instrument, such as a Mehari clamp).

The correction is obtained in all the planes when the holes of the proximal bone fragment Sp (obtained by the first part **4**) are opposite the proximal through-orifices **1011** of the osteosynthesis plate **10** (FIG. **11**).

Indeed, as mentioned hereinabove, the relative arrangement between the two groups of through-orifices **42**, **56** of the surgical guide device **1** takes into account, on the one hand, the correction intended to be applied during the opening wedge osteotomy technique, and on the other hand, the relative arrangement of the two groups of through-orifices **1011**, **1012** of the osteosynthesis plate **10**.

Pins **7** are then inserted through these proximal through-orifices **1011** to maintain the opening (FIG. **12**).

The different fastening screws **102** are then successively inserted into the bone S, through the different orifices **101** of the osteosynthesis plate **10**.

When the osteosynthesis plate **10** is definitively fastened, if he wants to, the operator can fill the obtained opening with, for example, solid or injectable synthetic bone substitutes, bone grafts (iliac grafts).

If he wants to, after the opening, the operation may also use the second lower rod **84** to guide the insertion of a cannulated screw **103** through the hinge (FIG. **16**).

This cannulated screw **103** hence helps in maintaining the opening (or even also the bone substitute), in association with the osteosynthesis plate **10**.

This cannulated screw **103** has also for vocation to reinforce the integrity of the hinge, and hence to further reduce the risk of postoperative breaking. It also allows taking part to the integrity of the hinge and hence to the good opening value defined by the surgical guide device **1**.

Such a cannulated screw **103** may also be interesting within the framework of an intraoperative repair, in order to repair a hinge that would have broken despite the first lower rod **82** (after a too sudden movement, great opening, etc.).

Generally, the surgical guide device **1** hence helps the surgeon to make its operation in a precise and secure manner.

This surgical guide device has for interest to help the operator all along the opening wedge osteotomy operation (in particular for making the cut line and the opening), so as to precisely follow the preoperative planning.

This surgical guide device may be used to implement an opening wedge osteotomy technique on other bones, for example the distal femur, the wrist, the distal tibia.

This device also gives access to complex corrections in the three dimensions, with a continuous control of the operative process.

The invention claimed is:

1. A surgical method of opening wedge osteotomy, wherein said surgical method comprises:

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a) a preparation step, during which a surgical guide device is fastened against a surface of a bone, wherein said surgical guide device is placed against a patient's bone for performing the opening wedge osteotomy, said surgical guide device comprises:

a rear face (**11**) to be positioned against the surface of said bone (S), and

a window (**2**) for guiding a cut line intended to be made into said bone (S), wherein the window (**2**) has a plane (**2'**) defining a plane of the cut line in a bulk of the bone, wherein said guide window (**2**) is delimited by an upper edge (**21**) and a lower edge (**22**) of the surgical guide device, arranged opposite to each other and spaced apart from each other,

wherein said surgical guide device (**1**) comprises at least one distal tubular duct (**582**, **583**) that is arranged remote from the guide window (**2**) and that is directed in such a manner that the at least one distal tubular duct's longitudinal axis (**582'**, **583'**) intersects the plane (**2'**) of the guide window (**2**) in the bulk of the bone, in order to position at least one cut stop and/or hinge indication rod (**82**, **84**),

b) a bone osteotomy step, comprising:

b1—a cutting phase comprising guiding a cutting blade through the window and into the bone along the plane and towards a hinge of an osteotomy site to separate a proximal fragment of the bone from a distal fragment of the bone while being connected to each other by the hinge of the osteotomy, and

b2—a positioning of said at least one cut stop and/or hinge indication rod (**82**, **84**) through said at least one distal tubular duct (**582**, **583**) of said surgical guide device (**1**), temporarily implantable into said bone (S) and arranged to intersect the plane of the cut line in the bulk of the bone and to intersect the hinge of the osteotomy site,

c) a step of progressively opening the osteotomy site comprising moving the proximal fragment of the bone and the distal fragment of the bone away from each other about the hinge of the osteotomy site, up to a desired distance to achieve a desired correction of the bone,

d) a step of fastening an osteosynthesis plate against the surface of the bone comprising placing the osteotomy plate against the surface of the bone and in contact with the proximal and distal fragments of the bone, and fastening the osteotomy plate by inserting a plurality of screws through the osteotomy plate and into the proximal and distal fragments of the bone to freeze the proximal and distal fragments away from each other at the desired distance, and wherein said at least one cut stop and/or hinge indication rod (**82**, **84**) is remained inserted into the hinge of the osteotomy site during the step of progressively opening the osteotomy site and during the step of fastening the osteosynthesis plate against the surface of the bone.

2. The surgical method of opening wedge osteotomy, according to claim **1**, wherein said at least one cut stop and/or hinge indication rod (**82**) is inserted before the cutting is finished.

3. The surgical of opening wedge osteotomy, according to claim **1**, wherein said at least one distal tubular duct (**582**, **583**) of said surgical guide device (**1**) comprises at least two distal tubular ducts (**582**, **583**) that are arranged remote from the guide window (**2**) and that are directed in such a manner that their respective longitudinal axes (**582'**, **583'**) intersect

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the plane (2') of the guide window (2) in the bulk of the bone in order to each position a cut stop and/or hinge indication rod (82, 84).

4. The surgical method of opening wedge osteotomy, according to claim 3, wherein the direction of the longitudinal axis of said two distal tubular ducts (582, 583) are parallel to each other.

5. The surgical method of opening wedge osteotomy, according to claim 3, wherein a first cut stop and/or hinge indication rod (82) of said at least one cut stop and/or hinge indication rod (82, 84) is inserted before the cutting is finished and a second cut stop and/or hinge indication rod (84) of said at least one cut stop and/or hinge indication rod (82, 84) is inserted after the cutting is finished.

6. The surgical method of opening wedge osteotomy, according to claim 1, further comprising, after said step of progressively opening, using said at least one cut stop and/or hinge indication rod to guide the insertion of a cannulated screw therealong and through the hinge.

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7. The surgical method of opening wedge osteotomy, according to claim 1, wherein said at least one cut stop and/or hinge indication rod crosses an axis of rotation of the hinge at an intersection point within the hinge which is in a central portion (L1) of a length (L) of this hinge.

8. The surgical method of opening wedge osteotomy, according to claim 1, wherein said surgical guide device (1) comprises a proximal tubular duct (581) that is arranged directly underlying the guide window (2) and that is directed in such a manner that the proximal tubular duct's longitudinal axis (581') is parallel to the plane (2') of the guide window (2) in order to position a rod (81) helping in the guiding of the cut line, and

wherein, during said preparation step, the positioning of at least one rod comprises positioning a rod (81) helping in the guiding of the cut line.

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